

REMARKS

Applicants have amended claims 28 and 31; canceled claims 29-30, 32-37; and added new claims 40. Upon entry of this amendment, claims 28, 31, 38-40 will be pending.

Applicants wish to take this opportunity to thank Examiner Haq for discussing this case with the undersigned and provide valuable guidance.

The current amendment seeks to amend the claims of the present application to recite subject matter that applicants allege is patentably distinct from the subject matter involved in Interference No. 105,429 ("the '429 Interference"). The '429 Interference involves U.S. Patent No. 6,635,745 ("the '745 patent"), which is related to the present application in that both have the same disclosure and both claim priority from the same parent applications.

The present application was deemed allowable in an office action dated July 14, 2003. The Examiner thereafter suspended *ex parte* prosecution due to a potential interference. Since that time, the Examiner has sent applicants several communications continuing the suspension of prosecution.

The '745 patent was issued to applicants on October 21, 2003. On April 26, 2006, the Board of Patent Appeals and Interferences ("Board") declared the '429 Interference, involving the '745 patent and application serial no. 09/576,951 of Molnar-Kimber et al., a third party. As originally declared, the Count in the '429 Interference read as follows:

Sedrani claim 1. An immunogenic conjugate which is 1) rapamycin bearing an immunogenic protein at position 40 or 28; or 2) 40-O-(2-hydroxyethyl)-rapamycin bearing an immunogenic protein at position 28.

OR

Molnar-Kimber claim 33. A monoclonal antibody having binding specificity for a rapamycin, wherein said antibody is obtained using an immunogen comprising a molecule selected from the group consisting of a rapamycin having a linking group at the 42 position, a rapamycin having a linking group at the 31 position, and a rapamycin having a linking group at both the 42 position and the 31

position, wherein said molecule is conjugated to an immunogenic carrier material via said linking group.

In June 2006, Administrative Patent Judge Gardner-Lane asked each party involved in the '429 Interference to determine if the party would seek authorization to file a motion to add to the interference, or declare an additional interference involving any of U.S. patent applications 09/585,743 (the present application); 09/133,104; 10/124,386; 09/576,951; or 11/272,070. Attached is a copy of an "Order – Miscellaneous – Bd.R. 104(a)" (Paper 19), dated June 28, 2006, from the interference, in which the Board memorialized that each party in the interference indicated it did not wish to file any motion to add to the interference, or declare an additional interference involving, any of the aforementioned applications (including the present application). (See Paper 19 at page 2.)

In the '429 Interference, applicants thereafter filed "Sedrani Substantive Motion 1 (to substitute the count)" on August 28, 2006. The motion was supported by the "Declaration of Walter Schuler in Support of Sedrani's Motion to Substitute the Count" and the "Declaration of Achim A. Jungbluth in Support of Sedrani's Motion to Substitute the Count." In the motion to substitute the count, applicants sought to substitute the count with new count 2 as follows (text deleted from the original Count shown in strikethrough font):

Sedrani claim 1. An immunogenic conjugate which is 1) rapamycin bearing an immunogenic protein at position 40 or 28; ~~or 2) 40-O-(2-hydroxyethyl)-rapamycin bearing an immunogenic protein at position 28.~~

OR

Molnar-Kimber claim 33. A monoclonal antibody having binding specificity for a rapamycin, wherein said antibody is obtained using an immunogen comprising a molecule selected from the group consisting of a rapamycin having a linking group at the 42 position, a rapamycin having a linking group at the 31 position, and a rapamycin having a linking group at both the 42 position and the 31 position, wherein said molecule is conjugated to an immunogenic carrier material via said linking group.

The substitute count removes from the ‘429 Interference immunogenic conjugates which are 40-O-(2-hydroxyethyl)-rapamycin bearing an immunogenic protein at position 28. As shown in the Sedrani motion, applicants allege that such conjugates are separately patentable from immunogenic conjugates comprising rapamycin bearing an immunogenic protein at position 40 or 28 and monoclonal antibodies obtained using such rapamycin conjugates, remaining in the count.

On February 6, 2007, the Board granted Sedrani’s request for substitution of Count 2 for Count 1. Specifically, the Board indicated:

Sedrani has sustained its burden to show that *(1) the RAD conjugates of Count 1 are separately patentable from the subject matter of proposed Count 2*, and *(2) substitution of proposed Count 2 for Count 1 is appropriate in the circumstances of the interference.*

(See Paper 36 at page 16, *emphasis* added)

In separate paper (Paper 38) issued February 6, 2007, the Board entered judgment on priority against Sedrani in the ‘429 Interference as to Count 2.

Applicants present the amendments herein to direct the present claims to monoclonal antibodies that bind to a 40-O-alkylated rapamycin with low cross-reactivity for rapamycin. As supported by the Board decision in Paper 36, applicants assert that the amended claims are separately patentable from the subject matter of substitute count 2 in the ‘429 Interference.

In view of the conclusion of the '429 Interference and the fact the application was deemed allowable prior to the suspension of prosecution in connection with the '429 Interference, applicants request entry and favorable consideration of the claims as amended.

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